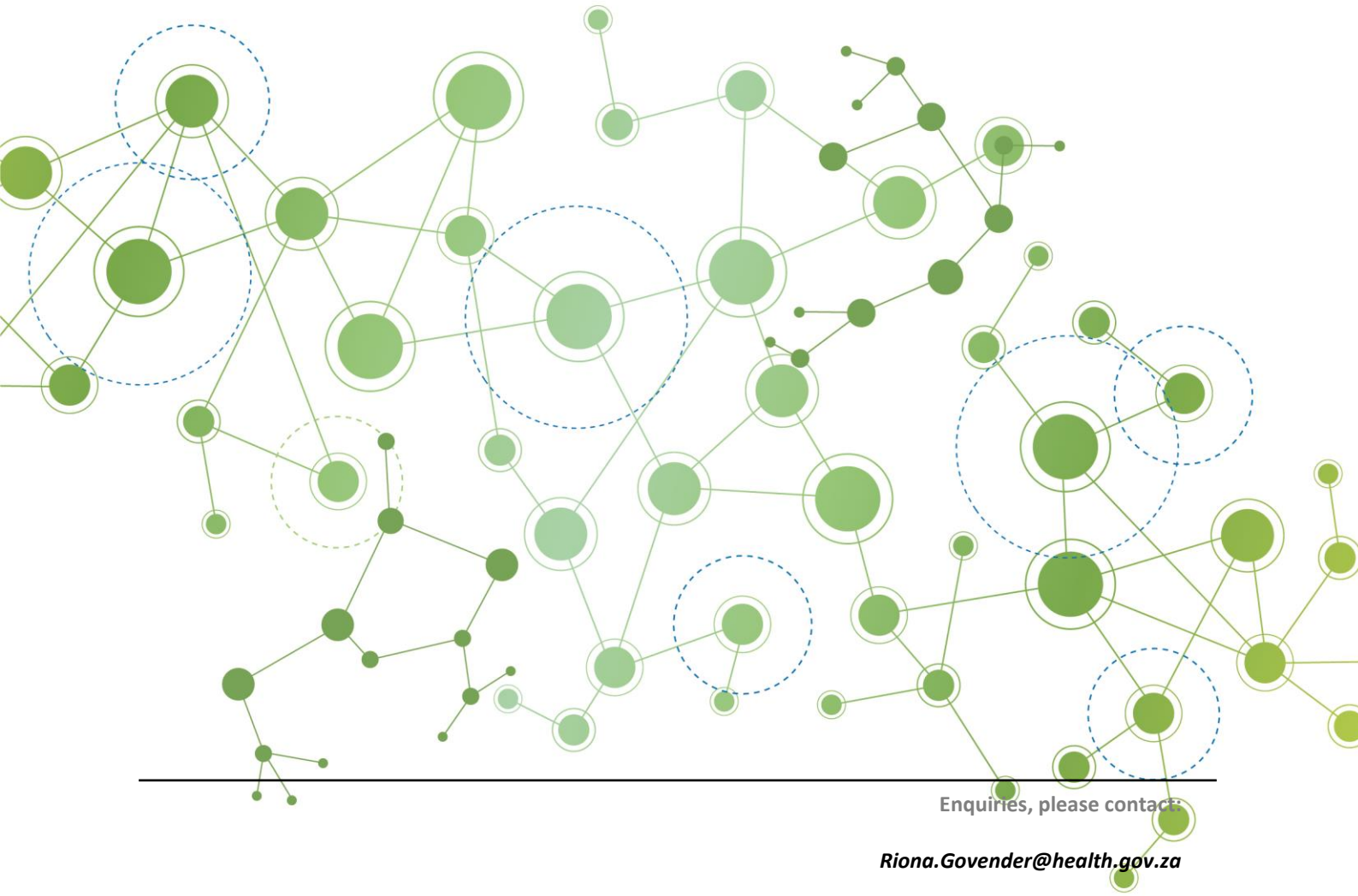
Access to Data Sourced from the National TB/HIV Dataset Guidance



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Document control

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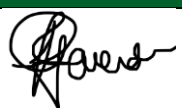
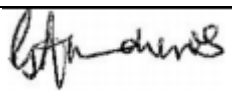
Version control

Date updated	Version	Updated by	Comment on changes
December 2020	1.0	Health Informatics Directorate	New document

Approval

Date approved	Version	Approved by	
December 2020	1.0	Dr Riona Govender	
December 2020	1.0	Dr Gail Andrews	

Background

The National Department of Health (NDOH) has invested significant resources to enable the collation of TB/HIV patient-level data at a National level. Data is centralised to provide a single, consolidated location for analysis of TB/HIV patient-level data. The aim is to use advanced analytics to improve TB/HIV patient health outcomes and programmatic/operational management.

Given that these data have been centralised to enable advanced analytics, it is critical that processes be institutionalised for requests from different health system stakeholders to utilise these data. Not only are these processes critical from a workflow and governance perspective, they also serve the critical role of protecting patient identifiable information (PII).

Considering the opportunities available for use of these data to improve patient health outcomes and programmatic management, the NDOH is committed to making data available to health system stakeholders that can support these aims. However, it is also the responsibility of the NDOH to safeguard patient information, in accordance with current legislation, and ensure that data is used in both an appropriate and reasonable manner within the public health context.

Policy considerations

Preservation of patient confidentiality, particularly identified clinical information of individual patients and all associated databases, is a statutory and policy obligation. The following legislative and policy prescripts vis-à-vis health data security and the protection of personal information, towards the protection of all South African citizens, are authoritative and are considered in this guidance document:

- The National Health Act 61 of 2003 (Section 74)
- The Public Service Act of 1994 (Chapter 5)
- The Protection of Personal Information Act 4 of 2013
- Management of Information Security Standards
- National Guidelines on Filing, Archiving and Disposal of Patient Records in Primary Health Care Facilities (2017)
- Guidelines of Information Security (Section 16: Third Party Access)

Other applicable legislative and policy prescripts include:

- Promotion of Access to Information ACT (PAIA) (Act 2 of 2000)
- Children's Act (Act 38 of 2005)
- Protection of State Information Bill (B6-2010)
- Minimum Information Security Standards (MISS)

Purpose

The purpose of this guidance document is to establish standardised processes for requesting data from the NDOH as sourced from the national TB/HIV patient-level dataset. Critical to this are considerations such as:

- Governing principles around access to, and sharing of, data as sourced from the national TB/HIV patient level dataset
- Processes for requesting data from the NDOH
- Policy around use of data shared with non-DOH and DOH entities

This guidance is primarily applicable to all non-Department of Health (DOH) organisations requesting data, and is applicable, in specific instances, to requests that originate from within the DOH (including Provincial Departments of Health. All other requests from outside the DOH will be treated as a request from a non-DOH organisation – this includes requests from other government agencies, parastatals, non-profit organisations, for-profit organisations, and other organisations in the public health space. Where guidance in the document does not make specific reference to either DOH or non-DOH requests, it refers to request from both parties.

Note that this guidance, and associated processes, do not apply in the following circumstances:

- Requesting access to the routine health information system, webDHIS, and any data contained within.
- Direct access, limited or otherwise, to the national TB/HIV patient level dataset as this will not be granted under any circumstance.
- Requests for access to local instances of the TB/HIV information systems at sub-national levels (i.e. a facility or sub-district instance of TIER.Net).[1]
- Service delivery staff that require access to patient-level data to perform service delivery duties.[2]

Governing principles

This section outlines the underlying principles and framework that must be used to structure requests for data. It is essential that data requestors familiarise themselves with these principles to understand processes and related requirements.

TB/HIV Information Systems (THIS) Data Request Committee

The THIS Data Request Committee (TDRC) is comprised of NDOH managers from the Health Systems Governance and HRH (and within this, custodians of the TB/HIV information system), Health Programmes, and Primary Health Care branches.

[1] As established by Provincial Departments of Health and relevant TB/HIV information systems guidance documentation and Acess to the TB/HIV Electronic Patient Information System

[2] As established by Provincial Departments of Health.

This committee will review data requests as submitted using the **'Request Form: Access to non-routine TB/HIV information systems data from the National TB/HIV centralised dataset'** (Appendix A – referred to as the 'Request Form') on a routine basis. Note that any requests received without using the form will not be considered – this applies to requests originating from both non-DOH and DOH organisations/staff.

When reviewing requests, as communicated through the Request Form, the committee will consider the following:

- Reasonability of the request
- Risks to patient confidentiality (where applicable)
- Purpose of the request
- Applicability to current South African public health context
- Similarity to other requests received or work currently underway
- Innovativeness when compared with data routinely available through webDHIS aligned to the most recent version of the National Indicator Data Set (NIDS)
- Level of effort required on the part of the custodians of the TB/HIV information system to develop and disseminate the request for data
- Applicability of the request to the TDRC
- Ethics committee approvals, as well as reconciliation with existing NDOH ethics standards and protocols, where applicable
- Any other factors as determined to be applicable by the TDRC

The TDRC will meet either in-person or remotely every 2 months to review requests received using the Request Form as provided in Appendix A. In the event that there are no requests, the TDRC will not convene. Only when the TDRC, or a designee of the TDRC, has approved a Request Form can data be released to the requestor.

Identified and non-identified data

Identified information is data that can be used on its own or with other information to identify, contact, or locate a single patient, or to identify an individual in context.

Non-identified information is data that cannot be used on its own or with other information to identify, contact, or locate a single patient, or to identify an individual in context. This can be presented in patient-level disaggregation, or in an aggregated fashion.

Identified data

In the main, the NDOH will not release **identified information** given protections entrenched in the legislative and policy prescripts outlined earlier in this guidance document. However, where a request includes identified information, and is approved by the TDRC, further approval will then need to be sought from the Director-General of Health, or his/her designee.

Where the TDRC and the Director-General of Health approve the release of identified information, the NDOH will negotiate specific terms of the released data with the recipient. Before any identifiable information is released, both parties will be required to enter into a contractually binding

agreement that is agreeable to both parties. This will include a term in which the approval is applicable. No provision of access to data is considered permanent and may be revoked at any time.

Non-identified data

Requests for **non-identified, patient-level data** will be considered, but will be reviewed with additional scrutiny as release of any patient-level information presents risks to patient confidentiality. Moreover, the mechanics and logistics around sharing of non-identified, patient-data introduce further complications. Where these requests are received, the TDRC will consider whether these data can be provided in an aggregate fashion.

It is expected that requests for **non-identified, aggregate data** will constitute the majority of requests received by the TDRC. These requests will be considered in line with the considerations outlined in the *TB/HIV Information Systems (THIS) Data Request Committee* section.

Upon approval by the TDRC, the NDOH will make aggregate, non-identified data available, provided that the use of this information does not breach confidentiality and that the data cannot be connected to a person's identity. Where data allows for such a connection to be made, the NDOH may:

- Make available aggregated data over a broader geographical area
- Make available data over a longer period
- Make available data by broader categories
- Enter into a confidentiality agreement with the data requestor

Consideration of routinely available data

It is critical that before submitting a request for data, the requestee considers which data elements are already available in the routine health information system (webDHIS).

Requests for data that appear to mimic what is routinely available will not be considered. If the requestor still requires access to this routine health information, processes to request access to routine data (https://za.dhis.dhmis.org/dhis-web-commons/security/login.action) must be followed.

Moreover, the process for requesting data should not be considered as a 'workaround' to data requests not approved/granted through the routine health information system. NDOH management responsible for stewardship of the routine health information system will be part of the TDRC to actively adjudicate this.

Process

To ensure a common understanding between the TDRC and the requestor, and to support standardisation of the review process, the Request Form (Appendix A) must be filled in and submitted to the TDRC as per the process stipulated in the section below. It is important to note that, submission of a request does not guarantee approval by the TDRC. Where the TDRC determines it is necessary, the TDRC may request additional information on, or modifications to, the Request Form.

The following are the steps required to submit data requests:

Requests from within the DOH

1. Requestor downloads the **'Request Form: Access to non-routine TB/HIV information systems data from the National TB/HIV centralised dataset' (Appendix A)** from the TB/HIV information system support portal (https://www.tbhivinfosys.org.za/documents).
2. Requestor fills in the forms in accordance with directions on the form, as well as the considerations outlined in this guidance document.
3. Requestor e-mails the filled-in and signed form to the NDOH Director of Health Informatics - Dr Riona Govender at riona.govender@health.gov.za. The Requestor must also copy abraham.phakathi@health.gov.za.
4. Custodians of the TB/HIV information system will review, seek clarifications, and provide data as requested/discussed.
    a. Responses to requests will be provided within 5 business days, and depending on the complexity of the request, data will be provided within 10-15 business days of reaching agreement on the data to be provided.

Requests from non-DOH organisations

1. Requestor downloads the **'Request Form: Access to non-routine TB/HIV information systems data from the National TB/HIV centralised dataset' (Appendix A)** from the TB/HIV information system support portal (https://www.tbhivinfosys.org.za/documents).
2. Requestor fills in the forms in accordance with directions on the form, as well as the considerations outlined in this guidance document.
3. Requestor e-mails the filled-in and signed form to NDOH Director, Health Informatics - Dr Riona Govender at riona.govender@health.gov.za. The Requestor must also copy abraham.phakathi@health.gov.za and NIT_support@health.gov.za
4. Requestor will receive confirmation of receipt from the NDOH within 5 business days.
5. The TDRC will convene every 2 months to review Request Forms received.
6. The TDRC decides on whether the request is approved or not, or if additional information is required.
7. The TDRC will notify the requestor of the final decision within 10 business days of the TDRC outcome.
    a. If **not approved**, the requestor may ask clarifying questions, but the NDOH is not obliged to provide a detailed explanation as to why the request was denied.
    b. If **approved**, the requestor will be contacted, and timelines for provision of the data will be agreed up on.
        i. The requestor may be asked to fill in additional documentation, and the NDOH may require a confidentiality or advanced data user agreement to be signed.
        ii. Depending on the complexity of the request, data will be provided within 10-15 business days of the decision having been communicated to the requestor.

Filling in the Request Form

Critical to the process of requesting and providing data, is establishing a common understanding between both NDOH and the requestor of what exactly is being requested, and thus what requires review by the TDRC. The following provides guidance on information required when completing the form:

- Purpose of the request
    - Provide a brief motivation for requesting the data, including the intended use of the data, as well as any other individuals who require access to the specific dataset to be provided. Include a link to the requesting organisation's website.
    - Critically, the requestor must indicate if the data is for 'research' or 'operational' or 'other' processes. If 'other' is specified, further detail must be provided.
        - If research, protocols are to be submitted with the Request Form.
- Type of data requested
    - Provide detail regarding the data points/elements that are required. What, specifically, does the requestor require? This should be detailed to ensure that a data definition can be developed, and appropriately translated into code.
    - Please note that the TB/HIV information system includes select data points for **presumptive TB, DS-TB treatment, HIV testing,** and **ART** programme areas.
        - Before filling in this section, the requestor should cross reference the specific data points/elements requested with what is available in the most recent version of NIDS.
- Data parameters
    - Period for which data is being requested.
    - Is the request once-off, or will subsequent requests for the same data be made on an ongoing basis?
        - Note that additional scrutiny and reasonability considerations will be applied for 'repeat' requests.
    - Specifics on the type of data requested.
        - This section must include detailed information that will be used to extract and/or analyse the data per the request. As such critical considerations include:
            - Level of analysis (provincial, district, sub-district, or facility)
            - Type of disaggregation (gender, age, disease status, etc.)
            - If 'Repeat' was selected, at what frequency
            - Inclusion and exclusion criteria (where applicable)
        - Note that more complicated analyses will require additional processing time.

Use of data

Critical to the agreement between the requestor and the NDOH is adherence to prescriptions around the use of information provided, as well as a common understanding with respect to how the requestor intends to use the data. For example, where a requestor indicates that data will be used for 'operational' or 'research' purposes, it is expected that if a deviation is required in terms of the communicated use, the requestor must re-submit the Request Form to the TDRC.

Any use of data outside of the key tenants outlined below will be considered breach of the agreement, and may result in sanction, as well as denial of future data requests.

Use of data within the DOH

Where data is requested by the DOH, and is requested for use within the DOH for analysis and programmatic/operational management, the following is requested of the requestor:

- Data to be disseminated internally only, otherwise governance processes as established in this document could be (mistakenly or purposely) subverted. Non-DOH organisations requiring access to these data must follow the processes as outlined for non-DOH organisations.
- Reasonable attempt is made to come to a common understanding around messaging of said data points with relevant entities to ensure that there is no misunderstanding in the data points shared.
- Data be stored securely.
- Source of the data (TB/HIV Information System) and date of access is clearly indicated.
- Where publication is involved, prescripts in the above section are adhered to.
- Data quality issues are raised with the TDRC.

Use of data outside the DOH

By sending in the Request Form, non-DOH users agree to the following provisions around data supplied by the NDOH:

- The NDOH remains the owner of the data provided.
- The requestor will only provide access to the dataset to specific individuals listed in the Request Form.
- The requestor will not use or disclose the data for any purpose other than what was permitted by the TDRC for which written approval was provided.
- The requestor will not release the data to a third party that is not included in the Request Form and agreed to in writing with the NDOH. If a third party is to receive data, they will also need to complete a Request Form and will be required to follow all prescribed processes detailed in this guidance document.
- The requestor agrees that the NDOH will be provided opportunity to comment and give feedback prior to the finalization of any report/publication produced using data as provided by the NDOH.

- The requestor agrees that the NDOH will have 20 working days to provide feedback on any report/publication, and that reports/publications will not be published without integrating NDOH feedback.
- The requestor will ensure that the NDOH is acknowledged in any output resulting from the data.
- The requestor will communicate any data quality issues identified to the NDOH.
- The requestor agrees that any use of the data or reliance by the requestor on any of the data is at the requestor's own risk, and that the NDOH shall not be held liable for any loss or damage howsoever arising as a result of such use.
- The requestor agrees that no statement will be made, nor permit others to make statements indicating or suggesting that interpretations/views drawn from the findings are those of the NDOH.
- The requestor agrees that all data from the NDOH are to be treated as confidential and used in accordance with the following security standards:
    - At a minimum, the database must have user-level security, may not be housed on laptops or external media unless these are encrypted. Ideally the data should be stored on a central server with restricted access and not be stored on portable computer equipment like memory sticks, external hard drives and laptops.
    - Data must be password protected and such passwords are not to be shared with anyone other than the principle user.
    - Data may not be linked to personally identifiable records for any other source unless prior approval has been explicitly granted by the TDRC.
    - At a minimum, data will be stored with AES encryption e.g. 7-zip, and 15-character passwords that include numbers, special characters and letters.
    - Passwords and files may not be provided together, but by using two different methods of communication.
- The NDOH reserves the right to set conditions in which its staff should be invited to participate in any research that uses the data they have generated with a view to co-authorship of outputs.
- The requestor accepts that this data is routinely collected as part of service delivery and therefore the data may be imperfect.
- The requestor accepts that failure to adhere to the prescripts outlined in this document, and in the Request Form, can and may be sanctioned.

Publication

Whether within, or outside of the DOH, data may only be used for publication (including conference presentations) if:

- Publication was specifically referenced on the Request Form.
- Publication is agreed to, in writing, between the Requestor and a designated representative of the TDRC.

- The TDRC has been given the opportunity to comment on any evaluation, analysis, or interpretation.
- The source of these data, namely the NDOH, is clearly indicated and referenced in the publication.
- Authorship concerns are agreed to, in writing, with a designated representative from the TDRC.

Any publication done outside of these key tenants will be considered breach of the agreement, and may result in sanction, as well as denial of future data requests.

Appendix A: Request Form

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Request Form: Access to non-routine TB/HIV information systems data from the National TB/HIV centralised dataset

The following form is to be used by any entity (individual or organisation) requesting access to non-routine data sourced from the TB/HIV information system (THIS). Please note that a request for access to data does not automatically indicate that access will be granted. Requests will be reviewed and approved by the THIS Data Request Committee (TDRC) and relevant National Department of Health (NDOH) Managers. For additional detail, please add additional pages with appropriate headings. For additional detail on the process of requesting data, as well as other critical considerations, please refer to the **Requesting Access to Data Sourced from the National TB/HIV Centralised Dataset** guidance document.

First Name: _____ Surname: _____

Organisation: _____ Position: _____

Phone Number: _____ E-mail: _____

Purpose of the request:

Provide a brief motivation for requesting the data, including the intended use of the data, and any other individuals (aside from yourself) that will have access to the data to fulfill the use as detailed in this form.

Type of data required:

Please provide detail regarding the type of data required. Please be reminded that the TB/HIV information system includes select data points for presumptive TB, DS-TB treatment, HIV testing, and ART programme areas. For reference, please review the most recent National Indicator Data Set (NIDS).

Data parameters:

Indicate the time period for which the data is requested:

Start date (dd/mm/yyyy): _____ End date (dd/mm/yyyy): _____

Indicate the frequency at which the data is required. Note that additional scrutiny and reasonability considerations will be applied to 'Repeat' requests:

Once-off ☐ Repeat ☐

Please indicate specifics around the data required, including level of analysis (i.e. provincial, district, etc.) as well as the type of disaggregation required (i.e. sex, age, disease status, etc.). Note that further detail, and or more complicated analyses, will require additional processing time. If 'Repeat' above, at what frequency?

By signing this form, the entity agrees that:

- The NDOH is the owner of the data set, and the entity is fully aware of, and agrees to, all provisions in the Requesting Access to Data Sourced from the National TB/HIV Centralised Dataset guidance document.
- The data set may not be given to third parties. In order for third parties to gain access to the data, they must complete this form.
- The data set may not be used for purposes other than what is outlined, and approved, in the Request Form.
- The NDOH will have the opportunity to give feedback on any reports or publications prior to finalisation or submission. This feedback will be provided by the NDOH within 20 working days of receiving the materials for review.
- The NDOH will be acknowledged in any output resulting from the use of the data set.
- Data sets provided are to be treated as confidential and must be secured with user access control and password protection.
- Data may not be linked to any personally identifiable information from other sources without permission from the NDOH.
- Data is collected as part of service delivery and is routinely updated, and therefore data quality is imperfect.
- Violation of any of the terms set forth can result in legal action.

Signature: _____ Date: _____

Approved: Y / N **Approving Manager:** **Form updated:**
Approval Date: _____ _____ _____ June 2020